

# HOUSE BILL 868

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CF SB 163

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By: **Delegates Montgomery, Carr, Frick, George, Heller, Howard, and Manno**  
Introduced and read first time: February 10, 2010  
Assigned to: Health and Government Operations

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## A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Pharmacy – Wholesale Distributors – Accreditation and**  
3 **Reciprocity**

4 FOR the purpose of altering certain circumstances when the State Board of Pharmacy  
5 may grant “deemed status” to wholesale distributors; requiring wholesale  
6 distributors that receive a permit by reciprocity to comply with certain  
7 requirements; requiring wholesale distributors that are not eligible for  
8 reciprocity to be accredited; requiring the Board to grant “deemed status” to  
9 certain wholesale distributors under certain circumstances; altering the  
10 definition of “deemed status” and defining certain other terms; and generally  
11 relating to the accreditation of and granting of reciprocity to wholesale  
12 distributors of prescription drugs.

13 BY repealing and reenacting, without amendments,  
14 Article – Health Occupations  
15 Section 12–6C–01(a), (h), (n), (v), and (w)  
16 Annotated Code of Maryland  
17 (2009 Replacement Volume)

18 BY repealing and reenacting, with amendments,  
19 Article – Health Occupations  
20 Section 12–6C–04  
21 Annotated Code of Maryland  
22 (2009 Replacement Volume)

23 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
24 MARYLAND, That the Laws of Maryland read as follows:

25 **Article – Health Occupations**

26 12–6C–01.

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (a) In this subtitle the following words have the meanings indicated.

2 (h) "Facility" means a facility of a wholesale distributor where prescription  
3 drugs are stored, handled, repackaged, or offered for sale.

4 (n) "Pedigree" means a document or electronic file containing information  
5 that records each wholesale distribution of a prescription drug.

6 (v) (1) "Wholesale distributor" means a person that is engaged in the  
7 wholesale distribution of prescription drugs or prescription devices.

8 (2) "Wholesale distributor" includes:

9 (i) A manufacturer;

10 (ii) A repackager;

11 (iii) An own-label distributor;

12 (iv) A private-label distributor;

13 (v) A jobber;

14 (vi) A broker;

15 (vii) A warehouse, including a manufacturer's or distributor's  
16 warehouse;

17 (viii) A manufacturer's exclusive distributor or an authorized  
18 distributor of record;

19 (ix) A drug wholesaler or distributor;

20 (x) An independent wholesale drug trader;

21 (xi) A third party logistics provider;

22 (xii) A retail pharmacy that conducts wholesale distribution, if  
23 the wholesale distribution business accounts for more than 5% of the retail  
24 pharmacy's annual sales; and

25 (xiii) A pharmacy warehouse that conducts wholesale  
26 distribution.

1 (w) "Wholesale distributor permit" means a permit issued by the Board  
2 under this subtitle to distribute prescription drugs or prescription devices into, out of,  
3 or within the State as a wholesale distributor.

4 12-6C-04.

5 (a) (1) In this section the following words have the meanings indicated.

6 (2) "Accreditation organization" means a private entity that:

7 (I) **IS RECOGNIZED BY THE BOARD; AND**

8 (II) **[conducts] CONDUCTS** inspections and surveys of wholesale  
9 distributors based on nationally recognized and developed standards.

10 (3) "Deemed status" means a status under which a wholesale  
11 distributor may be exempt from **INITIAL AND** routine [inspections and other permit]  
12 **INSPECTION** requirements [of the Board] **UNDER THIS SUBTITLE.**

13 (4) **"SUBSTANTIALLY EQUIVALENT" MEANS THAT THE LAWS OF**  
14 **ANOTHER STATE ARE EQUAL TO OR MORE STRINGENT THAN THE LAWS OF THIS**  
15 **STATE AND REQUIRE, AT MINIMUM, PEDIGREES, ROUTINE INSPECTIONS OF**  
16 **WHOLESALE DISTRIBUTORS, OPERATION OF WHOLESALE DISTRIBUTORS IN A**  
17 **COMMERCIAL NONRESIDENTIAL FACILITY, AND SECURITY MEASURES.**

18 [(b) If the Board determines that the standards of an accreditation  
19 organization are equal to or more stringent than State permit requirements, the  
20 Board may:

21 (1) Accept the accreditation of a wholesale distributor by an  
22 accreditation organization as evidence that the wholesale distributor has met State  
23 permit requirements; and

24 (2) Grant the wholesale distributor deemed status.]

25 (B) **THE BOARD MAY ONLY GRANT DEEMED STATUS TO A WHOLESALE**  
26 **DISTRIBUTOR THAT IS:**

27 (1) **CURRENTLY ACCREDITED BY AN ACCREDITATION**  
28 **ORGANIZATION, WHEREVER THE WHOLESALE DISTRIBUTOR IS LOCATED; OR**

29 (2) **LOCATED IN A STATE THAT HAS REQUIREMENTS THAT ARE**  
30 **SUBSTANTIALLY EQUIVALENT TO THE REQUIREMENTS OF THIS STATE.**

1           (c)   **(1)**   The Board may issue a **WHOLESALE DISTRIBUTOR** permit by  
2 reciprocity to a wholesale distributor who holds a license or permit under the laws of  
3 another state if the Board determines that the requirements of that state are  
4 substantially equivalent to the requirements of this State.

5                   **(2)**   **A WHOLESALE DISTRIBUTOR THAT RECEIVES A PERMIT BY**  
6 **RECIPROCITY SHALL COMPLY WITH THE REQUIREMENTS OF § 12-6C-05(E) AND**  
7 **(F) OF THIS SUBTITLE.**

8                   **(3)**   **IN ADDITION TO MEETING THE REQUIREMENTS UNDER THIS**  
9 **SUBTITLE, A WHOLESALE DISTRIBUTOR LOCATED OUT-OF-STATE THAT IS NOT**  
10 **ELIGIBLE FOR RECIPROCITY SHALL BE ACCREDITED BY AN ACCREDITATION**  
11 **ORGANIZATION.**

12                   **(4)**   **THE BOARD SHALL GRANT DEEMED STATUS TO A**  
13 **WHOLESALE DISTRIBUTOR THAT:**

14                           **(I)**   **IS CURRENTLY ACCREDITED BY AN ACCREDITATION**  
15 **ORGANIZATION; OR**

16                           **(II)**   **HAS BEEN GRANTED RECIPROCITY BY THE BOARD.**

17           (d)   The Board or its designee may inspect a wholesale distributor who is  
18 accredited or has been issued a permit by reciprocity to:

19                   (1)   Determine compliance with any permit requirement under this  
20 subtitle; or

21                   (2)   Investigate a complaint.

22                   **SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect**  
23 **October 1, 2010.**